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Agricultural Science Transactions: Nuts and Bolts of IP Protections and Licensing

Historical Methods of Plant Protection (Pre-GMO)

- Plant Breeders Rights/Plant Variety Rights—
 - Sexual Reproduction
 - Protects Plant Varieties, But with Exceptions (research and saved seed), Not as Strong as Traditional Patents
 - Essentially Derived Varieties
 - US—Plant Variety Protection Act
- Plant Patents—Assexual Reproduction
 - US—Recognizes



Breeders Rights "The Breeders' Privilege" UPOV 91, Art 15(1)

- (Compulsory exceptions) The breeder's right shall not extend to
 - (i) acts done privately and for non-commercial purposes,
 - (ii) acts done for experimental purposes and
 - (iii) acts done for the purpose of breeding other varieties, and, ...[derived varieties aside], acts ...[of commercial exploitation].. in respect of such other varieties.
- It is **never** an infringement of a PVP right to use the variety for further breeding.
- It is **generally** not an infringement of a PVP right to exploit or sell the new variety bred.
 - Exception for 'essentially derived varieties'

Essentially Derived Varieties

"a variety shall be deemed to be essentially derived from another variety ("the initial variety") when

- "it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,
- it is clearly distinguishable from the initial variety and
- except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety." [Article 14.5.b, UPOV 1991]



GMOs - The New Frontier

- Genetically Modified Organisms
 - Insertion of Genes of Genetic material in a specific site in the plant DNA
- Traditional Patent Rights Extended to GMO Plants
 - Making, Using, Selling, Importing
- Key Research Crops: Arabidopsis, Tomatoes, Rice, Tobacco
- · Key Commercial Crops: Corn, Soy, Cotton, Canola
- Patent Protection can occur in two stages:
 - Invention of the Gene/Trait
 - Transgenic Plant itself



Key Terminology

- Genes & Traits
 - Composition of Matter Claims
 - Up-Regulation vs. Down-Regulation
 - Homology & Orthology: Defining the Gene Sequence within the same plant or a different plant to yield the same function
 - Traits confer Function Yield and Stress Tolerance,
 Pathogen Resistance, Insect Resistance; Herbicide
 Tolerance (Round-Up™)
- Enabling Technology
- Events = Transgenic Plants
- Overlaps with Plant Breeders Rights
 - Example: Farm Saved Seed



GM Pipeline – Discovery to Commercial Launch

- 7-10 Year Timeline
- "Phases"
 - Phase I Discovery, Green house, Non-Commercial Field Trials
 - Phase II Commercial Field Trials (Standard 2 years)
 - Phase III Regulatory Field Trials (Internal Regulatory Packages) with elite Germplasm
 - Phase IV Commercial Bulk-Up;
 Registration/Deregulation & Commercial Launch



License Grants

- Exclusivity is Key for Genes
 - Gene Shuffling is an Issue
 - Homology provides a "Zone of Exclusivity"
 - Capture the Gene, not just the "Function" (i.e. the Trait)
 - Typically crop limited
- Enabling Technology provides Freedom To Operate
 - Nonexclusive license permissible
 - Trade Secrets may also provide protections



Value Capture

- Trait Revenue & Value Share
 - Growers retain a portion of value share
- Stacking Traits & Multi-Gene Traits Allocation Issues
- Enabling Technology Net Sales
- With GM plants, value capture does not extend beyond patent life



Grant-Back Obligations

- Patentable vs. Non-Patentable Improvements
- Materials Transfer



Additional Items

- Regulatory & Stewardship
 - Importance is driven by scope of exclusivity and number of commercial partners
- Termination and Destruction of Biological Materials
 - Gene by Gene basis
 - Crop basis
 - Destruction/Return of Biological Materials
- Nonassignability of Biological Materials



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